HFI-35

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

M2199N

Refer to: CFN 1123735

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4040

November 13, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. John Byrnes, President/CEO
Lincare, Incorporated
19337 U.S. 19 North, Suite 500
Clear Water, Florida 33764

Dear Mr. Byrnes:

The Food and Drug Administration (FDA) conducted an inspection of your Virginia Beach, Virginia facility on October 30 through November 12, 1998. That inspection found deviations from the Current Good Manufacturing Practice Regulations (CGMP) (Title 21, Code of Federal Regulations (CFR), Parts 210 & 211) that were discussed with local plant management. (See the enclosed Form FDA-483.) These deviations cause your Oxygen, USP to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act). The deviations included the following:

1. Failure to establish accurate and complete batch production records for each batch of Oxygen, USP, including documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished.

2. Failure to follow written production procedures.

3. Failure to maintain complete written procedures for production and process control, proper equipment performance, and CGMP training.

The above listed violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations. Federal agencies are advised of the issuance of all Warning Letters concerning drugs so that they may take this information into account when considering the award of contracts.

Your voluntary corrections of some of the aforementioned deviations by destroying (venting) medical oxygen cylinders on the premises during the inspection, recalling of high-pressure oxygen cylinders, ceasing the manufacture of high-pressure medical oxygen at this and your other facilities, and your suspensing the filling of vehicle mounted liquid oxygen tanks at this facility, have been documented in our records. However, continuing CGMP violations at your manufacturing facilities are of concern to the agency. We strongly recommend that you assure that your facilities are in compliance with all regulations before initiating further manufacture of Oxygen, USP.-

By copy of this letter, we are advising the Health Care Financing Administration (HCFA) that our inspection revealed significant deviations from the Act. They may elect to defer or discontinue payment for any health care product in violation of state or federal law.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction. Enclosed is a compressed medical gases guideline which discusses the applicability of the CGMPs to medical gas manufacturers.

Please notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, Northern Virginia Resident Post, 101 West Broad Street, Suite 400, Falls Church, Virginia 22046, to the attention of Gerald W. Miller, Compliance Officer. Mr. Miller can be reached at (703) 235-8440, extension 504.

Sincerely,

Elaine Knowles Cole
Director, Baltimore District

Enclosures: Form FDA-483 (Inspectional Observations)
Fresh Air '98'

cc: Ms. Emelita P. Latham, Area Manager
Lincare, Incorporated
301 Cleveland Place, Suite 102
Virginia Beach, Virginia 23462